Safety During Regional Anesthesia

What Do We Know and How Can We Improve Our Practice?

Dan Benhamou, MD, Yves Auroy, MD, PhD,† and René Amalberti, MD, PhD‡*

Although not all experts accept this thesis,[1] most support the idea that mortality after general anesthesia (GA) has significantly decreased within the last 20 years.[2,3] Although the intuitive response suggests that the safety of regional anesthesia (RA) has improved similarly, our knowledge is much weaker. What is well established is that mortality associated with RA is less than with GA, especially in certain populations such as obstetric patients,[4] but it is less apparent if mortality associated with RA has decreased over the years. Despite safety recommendations[5] and the widespread availability of capnography and pulse oximetry in the 1990s, outcome for neuraxial cardiac arrest was not significantly different between the 1980s and 1990s claims in the US Closed Claims database.[6] It is also unclear if the rate of severe morbidity after RA has diminished in recent years. Some investigators have noted that the incidence of serious complications of obstetric epidural analgesia has not changed over a 17-year study period.[7] In addition, it has been shown that the rate of pregnancy-related neurological complications after epidural used for labor analgesia has not changed substantially over the years.[8] By contrast, the review by Ruppen et al[9] of nearly 1.4 million epidurals for obstetric anesthesia/analgesia suggests that adverse events were 4 times more frequent in studies published before 1990 when compared with the more recent ones. We also have limited information to suggest that the rate of peripheral nerve block–related complications is decreasing over the years.

The article by Barrington et al[10] in the November–December 2009 issue of *Regional Anesthesia and Pain Medicine* shows disappointingly that the incidence of neurological complications associated with peripheral nerve blocks seems very similar to what has been obtained in previous studies. This is surprising and disappointing because one might have expected that RA-associated neurological complications should have decreased for several reasons. First, improved safety advances for both GA and RA (eg, high-quality monitoring, postoperative surveillance, less toxic drugs, technical advances, etc) have emerged over the last 20 years and were expected to have positive effects on RA-induced morbidity and mortality. There has also been an increased use of peripheral nerve blocks everywhere in the world, and given the usual relation between volume and better outcomes, improved practice patterns and greater safety were expected. Data from large studies, however, do not support these expectations. The Auroy et al[11] study described cases collected in 1998–1999, whereas the Capdevila et al[12] study performed in the early 2000 period reported complication rates that are similar to those described by Barrington et al.[10] In other words, no major change in RA-associated mortality and morbidity can be seen over a 10-year time frame. Why does the rate of complications remain unchanged? Is it only a "technical" issue related to the statistical difficulty to detect subtle changes, or is this a real plateau as suggested by the very wide confidence interval obtained in the study of Barrington et al[10] (95% confidence interval, 0.08–1.1:1000)? Why do technical advances produce such profound changes in the GA area and yet are apparently ineffective for improving safety in the field of RA?

In the Barrington et al[10] study, two thirds of blocks were performed using ultrasound guidance, but the incidence of neurological complications was overall unchanged, and 2 of 3 neurological complications occurred with ultrasound use. This has also been observed in another recent Australian study in which the incidence of neurological complications occurring after 1000 ultrasound-guided blocks was in the range of the usual frequency obtained with non–ultrasound-guided blocks.[13] As noted above, even with the already large numbers of patients included in these 2 studies, their power is likely insufficient given the baseline low frequency of events. This might be of paramount importance because most experts expect that the use of ultrasound will lead to a decrease in these complications.

From the *Assistance Publique-Hôpitaux de Paris, AP-HP, Hôpital Bicêtre, Département d'Anesthésie-Réanimation, Université Paris XI, Le Kremlin-Bicêtre; †Service d'Anesthésie-Réanimation, Hôpital d'Instruction des Armées Percy; Clamart; and ‡Patient Safety, Haute Autorité de Santé (HAS), Saint Denis La Plainf, France.
Accepted for publication August 26, 2009.
Address correspondence to: Dan Benhamou, MD, Département d'Anesthésie-Réanimation, CHU Bicêtre, 78, Rue du Général Leclerc, 94275 Le Kremlin Bicêtre, France (e-mail: dan.benhamou@bct.aphp.fr).

ISSN: 1098-7339
DOI: 10.1097/AAP.0b013e3181c99564

However, if one goes back to the introduction of nerve stimulation in the early 1980s, there was (immoderate) enthusiasm as to the benefits expected to occur with the use of this technique. Unfortunately, the data do not demonstrate significant differences in neurological outcomes when nerve stimulation was compared with the more traditional paresthesia technique.[14] Compère et al[15] in an article published in 2009 also found that major complications after the use of continuous sciatic nerve block performed using nerve stimulation are still not rare. The incidence rates of severe neuropathy or infectious complications were, respectively, 5 in 1000 and 2.5 in 1000. It is thus not the first time that we disappointingly discover that technical advances associated with RA are not so easily associated with improved outcomes.

The use of ultrasound guidance is also often believed to protect against inadvertent intravenous injection. We and others have nonetheless described cases of local anesthetic systemic toxicity (LAST) in patients in whom the block was performed using ultrasound,[16,17] suggesting that this technique may not completely protect against the occurrence of this complication. In the article by Barrington et al,[10] 10 cases of systemic toxicity were observed, and 5 of 10 occurred despite ultrasound being used. The observed incidence of intravenous injection in ultrasound-guided blocks was slightly above 1 in 1000, which does not compare favorably with the rate found by Mulroy[18] for studies published after 1982 that report LAST after peripheral nerve blocks (ie, 0.75–2.0/1000). Moreover, data in the Barrington et al[10] study can be interpreted as being the largest series to date of systemic local anesthetic complications in patients undergoing ultrasound-guided blocks!

Reduction of the rate of complications related to intravascular injection of local anesthetic might well improve in future analyses. First, data presented by Barrington et al[10] might reflect the learning curve of RA ultrasound techniques, and it is likely that, with increasing skills, data will definitively show improved safety. Improved efficiency seems indeed associated with more precisely deposited local anesthetics. Casati et al[19] demonstrated that ultrasound guidance provides a 42% reduction in the minimum effective anesthetic volume required to block the femoral nerve as compared with the nerve stimulation technique. Riazi et al[20] also demonstrated that a 5-mL volume of 0.5 % ropivacaine produced a slightly slower onset of interscalene blocks and more limited spread of the local anesthetic than 20 mL of the same solution but was associated with similar pain scores and less hemidiaphragmatic impairment. A very surprising recent article[21] has moreover shown that when performing an axillary plexus block, nerves can be blocked with as little as 1 mL of local anesthetic each. If these results are confirmed, then the risk of a toxic event after RA will likely completely disappear or decrease by at least 1 order of magnitude. Apart from the likely improved precision obtained with ultrasound, other recent technological changes may also decrease local anesthetic dosing and subsequent risk of LAST. Paqueron et al[22] indeed showed that using stimulating catheters decreases the median effective volume to block the sciatic nerve from 16.6 to 2.7 mL of ropivacaine, that is, a 6-times reduction of volume.

Apart from these technological improvements, are there other directions that should be suggested to continue toward better safety when performing RA? When using the human factors and system safety paradigm, we can view our work as procedural steps through organizations as static layers and compartments while safety is described through reporting systems, errors rates, audits, or quality systems.[23] The report by Barrington et al[10] lies in this heritage and undoubtedly brings some useful information. One major piece of information provided by this study is indeed related to the fact that follow-up allowed the separation of RA-related complications from other causes and demonstrated that the other causes were 9 times more frequent. This observation could be placed in parallel with studies performed in obstetrics,[8] which also showed that RA is often blamed but rarely responsible. Having demonstrated that anesthesia per se is a rare cause of postoperative complications may make anesthesiologists proud of what they have accomplished, but it is not enough and should not discourage them from participating in the global action to improve patient safety. Time-out before incision is an ideal moment for surgeons and anesthesiologists to anticipate critical intraoperative and postoperative events[24] and to share concerns about actions that might be associated with complications (positioning, tourniquet).

Another strength of the Barrington et al[10] study is in the description of a Web-based registry, which leads to the possibility to collect and analyze large numbers of blocks. Holzmueller et al[25] have already implemented a similar Web-based registry in the United States to collect a large number of errors in intensive care units. It is clear that these registries have the potential not only to improve our knowledge but also to build a culture of safety and proactively monitor adverse events and outcomes. The use of a Web-based system does not add very much in itself but probably simplifies declaration and consequently might increase the number of cases and/or the quality of data collected. We have no doubt that our Australian colleagues will succeed in obtaining excellent data.

It may be, however, that these strategies have limited potential to carry us into the future. Regional anesthesia requires specific skills and the use of devices of rapidly evolving technology, yet understanding what makes systems safe requires more than simple knowledge of the human-machine interface (ie, skills). A major advance in medical safety has been the recent recognition that error is strongly affected by adverse conditions of work and that a posteriori analysis can help to avoid future complications by developing strategies for reducing errors.[26] Production pressure and rapid change within an organization are well recognized causes, and studies have shown that human factors play a predominant role in the occurrence of major complications (or death) today.[2,27] However, anesthesia is indeed an already safe system, and it is postulated that organizational failures in such a safe system are not always preceded by errors, but are instead preceded by normal work and drifts into failure due to pressure of scarcity and competition.[23] Human factors can precipitate the occurrence of an adverse event, but they can also progressively erode the system toward a more risky environment. Changes and drifts may occur slowly and be subtle enough to remain invisible. Drifts may also be encouraged by technical expertise, which sometimes leads to physicians developing original and useful strategies, but may also sometimes lead to deviation from guidelines and adoption of unsafe practice. To stop these drifts, we must analyze how physicians and other health care personnel behave and understand the world in which they act. Besides the now traditional strategy to improve safety, that is, incident reporting and audits (even if using highly sophisticated and modern communication strategies such as the Barrington et al[10] model of survey), focus should move toward evaluation of normal practice to detect where, how, and why deviations take place before any adverse event has occurred.

Moving toward a greater safety culture can also reduce the drift secondary to routinization and adaptation to pressure. Auditing normal practice can not only help to better apply treatments and restore health, but also emphasize gaps in safe

practice that occur every day. Failure to cleanse hands before clinical procedures is a common feature in anesthesia practice, and noncompliance is facilitated by a high intensity of patient care.[28] Implementing a simple hand sanitation strategy can, however, improve compliance and improve safety,[29] demonstrating that simple strategies can be efficient.

Moving forward, improved safety after RA should also include the patient. Informed consent, which aims to protect the autonomous choice of the patient, is traditionally defined in terms of 2 components: disclosure of information on a procedure, leading to the patient's understanding of this information, and authorization by the patient to proceed with treatment.[30] Disclosure includes information on the nature of a procedure, potential risks and benefits, and alternative treatments. We now have sufficient information on both outcome improvements associated with the use of perioperative RA and on risks associated with the technique. Why not share these data with the patient to help him (or her) decide.

REFERENCES

1. Lagasse RS. Innocent prattle. *Anesthesiology.* 2009;110:698–699.
2. Lienhart A, Auroy Y, Péquignot F, et al. Survey of anesthesia-related mortality in France. *Anesthesiology.* 2006;105:1087–1097.
3. Li G, Warner M, Lang BH, Huang L, Sun LS. Epidemiology of anesthesia-related mortality in the United States, 1999–2005. *Anesthesiology.* 2009;110:759–765.
4. Hawkins JL, Koonin LM, Palmer SK, Gibbs CP. Anesthesia-related deaths during obstetric delivery in the United States, 1979–1990. *Anesthesiology.* 1997;86:277–284.
5. Caplan RA, Ward RJ, Posner K, Cheney FW. Unexpected cardiac arrest during spinal anesthesia: a closed claims analysis of predisposing factors. *Anesthesiology.* 1988;68:5–11.
6. Lee LA, Posner KL, Domino KB, Caplan RA, Cheney FW. Injuries associated with regional anesthesia in the 1980s and 1990s: a closed claims analysis. *Anesthesiology.* 2004;101:143–152.
7. Jenkins JG. Some immediate serious complications of obstetric epidural analgesia and anaesthesia: a prospective study of 145,550 epidurals. *Int J Obstet Anesth*. 2005;14:37–42.
8. Holdcroft A, Gibberd FB, Hargrove RL, Hawkins DF, Dellaportas CI. Neurological complications associated with pregnancy. *Br J Anaesth*. 1995;75:522–526.
9. Ruppen W, Derry S, McQuay H, Moore RA. Incidence of epidural hematoma, infection, and neurologic injury in obstetric patients with epidural analgesia/anesthesia. *Anesthesiology.* 2006;105:394–399.
10. Barrington MJ, Watts SA, Gledhill SR, et al. Preliminary results of the Australasian regional anaesthesia collaboration: a prospective audit of more than 7000 peripheral nerve and plexus blocks for neurologic and other complications. *Reg Anesth Pain Med*. 2009;34: 534–541.
11. Auroy Y, Benhamou D, Bargues L, et al. Major complications of regional anesthesia in France: the SOS Regional Anesthesia Hotline Service. *Anesthesiology.* 2002;97:1274–1280.
12. Capdevila X, Pirat P, Bringuier S, et al. French Study Group on Continuous Peripheral Nerve Blocks. Continuous peripheral nerve blocks in hospital wards after orthopedic surgery: a multicenter prospective analysis of the quality of postoperative analgesia and complications in 1,416 patients. *Anesthesiology.* 2005;103:1035–1045.
13. Fredrickson MJ, Kilfoyle DH. Neurological complication analysis of 1000 ultrasound guided peripheral nerve blocks for elective orthopaedic surgery: a prospective study. *Anaesthesia*. 2009;64: 836–844.
14. Liguori GA, Zayas VM, YaDeau JT, et al. Nerve localization techniques for interscalene brachial plexus blockade: a prospective, randomized comparison of mechanical paresthesia versus electrical stimulation. *Anesth Analg*. 2006;103:761–767.
15. Compère V, Rey N, Baert O, et al. Major complications after 400 continuous popliteal sciatic nerve blocks for post-operative analgesia. *Acta Anaesthesiol Scand*. 2009;53:339–345.
16. Zetlaoui PJ, Labbe JP, Benhamou D. Ultrasound guidance for axillary plexus block does not prevent intravascular injection. *Anesthesiology.* 2008;108:761.
17. Loubert C, Williams SR, Hélie F, Arcand G. Complication during ultrasound-guided regional block: accidental intravascular injection of local anesthetic. *Anesthesiology.* 2008;108:759–760.
18. Mulroy MF. Systemic toxicity and cardiotoxicity from local anesthetics: incidence and preventive measures. *Reg Anesth Pain Med*. 2002;27:556–561.
19. Casati A, Baciarello M, Di Cianni S, et al. Effects of ultrasound guidance on the minimum effective anaesthetic volume required to block the femoral nerve. *Br J Anaesth*. 2007;98:823–827.
20. Riazi S, Carmichael N, Awad I, Holtby RM, McCartney CJ. Effect of local anaesthetic volume (20 vs 5 mL) on the efficacy and respiratory consequences of ultrasound-guided interscalene brachial plexus block. *Br J Anaesth*. 2008;101:549–556.
21. O'Donnell BD, Iohom G. An estimation of the minimum effective anesthetic volume of 2% lidocaine in ultrasound-guided axillary brachial plexus block. *Anesthesiology.* 2009;111:25–29.
22. Paqueron X, Narchi P, Mazoit JX, Singelyn F, Bénichou A, Macaire P. A randomized, observer-blinded determination of the median effective volume of local anesthetic required to anesthetize the sciatic nerve in the popliteal fossa for stimulating and nonstimulating perineural catheters. *Reg Anesth Pain Med*. 2009;34:290–295.
23. Dekker SWA. *Ten Questions About Human Errors—A New View of Human Factors and System Safety.* Aldershot, UK: Ashgate; 2004.
24. Haynes AB, Weiser TG, Berry WR, et al; Safe Surgery Saves Lives Study Group. A surgical safety checklist to reduce morbidity and mortality in a global population. *N Engl J Med*. 2009;360:491–499.
25. Holzmueller CG, Pronovost PJ, Dickman F, et al. Creating the Web-based intensive care unit safety reporting system. *J Am Med Inform Assoc*. 2005;12:130–139.
26. Vincent C, Taylor-Adams S, Stanhope N. Framework for analysing risk and safety in clinical medicine. *BMJ.* 1998;316:1154–1157.
27. Arbous MS, Meursing AE, van Kleef JW, et al. Impact of anesthesia management characteristics on severe morbidity and mortality. *Anesthesiology.* 2005;102:257–268.
28. Pittet D, Stéphan F, Hugonnet S, Akakpo C, Souweine B, Clergue F. Hand-cleansing during postanesthesia care. *Anesthesiology.* 2003; 99:530–535.
29. Koff MD, Loftus RW, Burchman CC, et al. Reduction in intraoperative bacterial contamination of peripheral intravenous tubing through the use of a novel device. *Anesthesiology.* 2009;110:978–985.
30. Housri N, Weil RJ, Shalowitz DI, Koniaris LG. Should informed consent for cancer treatment include a discussion about hospital outcome disparities? *PLoS Med*. 2008;5:e214.

